of enrofloxacin when intended for use in cattle.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Related tolerance.* See § 556.228 of this chapter.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 2.5 milligrams per kilogram (1.13 milligrams per pound) of body weight as an initial dose only.

(ii) *Indications for use.* Dogs for management of diseases associated with bacteria susceptible to enrofloxacin.

(iii) *Limitations.* As a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 10 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cattle*—(i) *Amount.* Single-dose therapy: 7.5 to 12.5 milligrams enrofloxacin per kilogram of body weight (3.4 to 5.7 milliliters per 100 pounds). Multiple-day therapy: 2.5 to 5.0 milligrams per kilogram of body weight (1.1 to 2.3 milliliters per 100 pounds) administered once daily for 3 to 5 days.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica, P. multocida,* and *Haemophilus somnus.*

(iii) *Limitations.* For subcutaneous use in cattle only. Do not inject more than 20 milliliters at each site. Do not slaughter within 28 days of last treatment. Do not use in cattle intended for dairy production. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. The effect of enrofloxacin on bovine reproductive performance, pregnancy, and lactation have not been determined. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals.

[55 FR 26683, June 29, 1990, as amended at 62 FR 38907, July 21, 1997; 63 FR 49003, Sept. 14, 1998]

§ 522.820 Erythromycin injection.

(a) *Sponsor.* See 061623 in § 510.600(c) of this chapter.

(b) *NAS/NRC status.* The conditions of use have been reviewed by NAS/NRC and found effective.

(c) *Dogs and cats*—(1) *Specifications.* Each milliliter of polyethylene glycol vehicle contains 100 milligrams of erythromycin base with 2 percent butyl aminobenzoate.

(2) *Conditions of use*—(i) *Amount.* 3 to 5 milligrams per pound of body weight, intramuscularly, two to three times daily, for up to 5 days.

(ii) *Indications for use*—(A) *Dogs.* For the treatment of bacterial pneumonia, upper respiratory infections (tonsillitis, bronchitis, tracheitis, pharyngitis, pleurisy), endometritis and metritis, and bacterial wound infections caused by *Staphylococcus* spp., *Streptococcus* spp., and *Corynebacterium* spp., sensitive to erythromycin.

(B) *Cats.* For the treatment of bacterial pneumonia, upper respiratory infections (rhinitis, bronchitis), secondary infections associated with panleukopenia, and bacterial wound infections caused by *Staphylococcus* spp. and *Streptococcus* spp., susceptible to erythromycin.

(iii) *Limitations.* Administer by deep intramuscular injection into the heavy muscles of the neck and limbs. Do not administer intravenously or intraperitoneally. Avoid subscutaneous use. Do not administer from moist or wet syringe. As with all antibiotics, appropriate in vitro culturing and susceptibility testing of samples taken before treatment should be conducted. Do not administer in conjunction with penicillin. As with all antibiotics, excessive continuous use may result in an overgrowth of nonsusceptible organisms. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Cattle.*—(1) *Specifications.* Each milliliter of nonaqueous, buffered, alcohol base sterile solution contains 200 milligrams of erythromycin base.

(2) *Related tolerances.* See § 556.230 of this chapter.

(3) *Conditions of use*—(i) *Amount.* 4 milligrams of erythromycin base per pound of body weight once daily for up to 5 days.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (shipping fever complex and bacterial

pneumonia) associated with *Pasteurella multocida* susceptible to erythromycin.

(iii) *Limitations.* For intramuscular use only. Do not use in female dairy cattle over 20 months of age. Do not slaughter treated animals within 6 days of last treatment. To avoid excess trim, do not slaughter within 21 days of last injection.

[58 FR 43795, Aug. 18, 1993, as amended at 66 FR 14073, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

§ 522.840 Estradiol.

(a) *Specifications.* Each silicone rubber implant contains 25.7 or 43.9 milligrams (mg) estradiol and is coated with not less than 0.5 mg oxytetracycline powder.

(b) *Sponsor.* See No. 021641 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.240 of this chapter.

(d) *Conditions of use.* For implantation in steers and heifers as follows:

(1) *Amount.* Insert one 25.7-mg implant every 200 days; insert one 43.9-mg implant every 400 days.

(2) *Indications for use.* For increased rate of weight gain in suckling and pastured growing steers; for improved feed efficiency and increased rate of weight gain in confined steers and heifers. No additional effectiveness may be expected from reimplanting in less than 200 days for the 25.7-mg implant or 400 days for the 43.9-mg implant.

(3) *Limitations.* For subcutaneous ear implantation in steers and heifers only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[69 FR 67818, Nov. 22, 2004]

§ 522.841 Estradiol benzoate.

(a) *Specifications.* The product consists of a vial of estradiol benzoate microspheres and a vial of diluent.

(1) Each milliliter (mL) of constituted suspension contains 10 milligrams (mg) estradiol benzoate.

(2) Each mL of constituted suspension contains 20 mg estradiol benzoate.

(b) *Sponsor.* See No. 067210 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.240 of this chapter.

(d) *Conditions of use.* It is used by subcutaneous injection as follows:

(1) *Suckling beef calves*—(i) *Amount.* 10 mg; 1 mL of the product described in paragraph (a)(1) of this section.

(ii) *Indications for use.* For increased rate of weight gain.

(iii) *Limitations.* For subcutaneous injection in the ear only. Do not use in calves intended for reproduction or calves less than 30 days old. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Steers fed in confinement for slaughter*—(i) *Amount*—(A) 20 mg; 1 mL of the product described in paragraph (a)(2) of this section for use in paragraph (d)(2)(ii)(A) of this section.

(B) 10 mg; 0.5 mL of the product described in paragraph (a)(2) of this section for use in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use*—(A) For improved feed efficiency.

(B) For increased rate of weight gain.

(iii) *Limitations.* For subcutaneous injection in the ear only. The use of 20 mg (1 mL) in steers does not provide additional rate of gain improvement over 10 mg (0.5 mL). Do not use in calves intended for reproduction or calves less than 30 days old. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Heifers fed in confinement for slaughter*—(i) *Amount.* One mL (20 mg) of product described in paragraph (a)(2) of this section.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* For subcutaneous injection in the ear only. Do not use in calves intended for reproduction or calves less than 30 days old. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[68 FR 49704, Aug. 19, 2003]